REMARKS

Claims 57-80 and 92-104 are pending in the present application, with claims 58-65, 69-80 and 92-97 being withdrawn from consideration. Claims 57, 66-68 and 98-104 were rejected. By the present amendment, claims 57 and 98 have been amended. This application continues to include claims 57-80 and 92-104.

The Examiner "notes that the kind code, issue date, and Name of Patentee or Applicant do not match the Patent Number for Cite No 1 of Applicant's 6 July 2010 IDS." The Examiner then changed citation number 1 to a reference that discloses a gas burner. The Examiner's assessment and change do not correspond to Applicants' intent. The IDS Form SB08a of July 6, 2010, properly identified the kind code as "E", which is the correct kind code for a reissue patent, as shown in the excerpt from the face page of the reissue patent below.

United States Patent [19] [11] E **Patent Number: Re. 33,258**
Onik et al. [45] **Reissued Date of Patent: Jul. 10, 1990**

[54] **IRRIGATING, CUTTING AND ASPIRATING SYSTEM FOR PERCUTANEOUS SURGERY**

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[73] Assignee: **Surgical Dynamics Inc.**, San Leandro, Calif.

[21] Appl. No.: **126,905**

[22] Filed: **Nov. 30, 1987**

Related U.S. Patent Documents

Reissue of:
[64] Patent No.: **4,678,459**
Issued: **Jul. 7, 1987**
Appl. No.: **633,514**
Filed: **Jul. 23, 1984**

[51] **Int. Cl.**[5] **A61B 17/32**
[52] **U.S. Cl.** **604/22**; 606/171
[58] **Field of Search** 128/305, 305.1, 751, 128/752, 755; 604/22

[56] **References Cited**

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[57] **ABSTRACT**

A percutaneous discectomy system **10** includes a discectomy device **12** having a needle **16** with a port **48** and a flared cutting edge **44** which is actuated past the port **48** to sever tissue provided adjacent thereto. An irrigation device is **18** are provided for irrigating the area adjacent the tip **46** of the needle **16** to assist a vacuum device **22** in aspirating the severed tissue away from the disc. The discectomy system **10** assists in the removal of herniated disc tissue in order to relieve pressure on the nerves located adjacent thereto. In addition, the needle **16** is flexible so that it can be temporarily or permanently bent around other body tissues such as the pelvis in order to access discs which are surgically hard to reach otherwise.

13 Claims, 3 Drawing Sheets

In this case, the patent number is Re. 33,258, and the number was entered in the form as 0033258. Re. 33,258 is a reissue of US 4,678,459. It is respectfully requested that the Examiner change the Form SB08a of July 6, 2010, to designate Re. 33,258, or US 4,678,459. Also, in either case, consideration of Re. 33,258/ US 4,678,459 is respectfully requested.

Claims 57, 66-68 and 98-100 were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter in view of the prior amendment to claims 57 and 98 In order to advance the prosecution of the present application, and without conceding the merits of the rejection, the final clause referencing "wherein the biopsy device is configured for ..." containing the offending language has been deleted in each of independent claims 57 and 98.

Accordingly, it is respectfully requested that the rejection of claims 57, 66-68 and 98-100 under 35 U.S.C. 101 be withdrawn.

Claims 57, 66-68, and 98-101 were rejected under 35 U.S.C. 103(a) as being unpatentable over Naslund (US 4,605,011) as modified by Gregoire, et al. (US 5,964,716; herein after Gregoire) and Dejter (US 4,989,614; hereinafter Dejter).

The Examiner states at page 11 of the present Office Action, "In response to arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references." The Examiner's reliance on this principle is misplaced. What the Examiner perceives as an attack on an individual reference is appropriate, for example, when Applicants are providing a counterpoint to the Examiner's assertion relating to a particular reference for disclosing a particular aspect of the invention. Further, for example, discussion of particular features, or lack thereof, with respect to a particular reference is appropriate in order to set up the

demonstration as to why one skilled in the art would not be motivated to combine the cited references.

In particular, the Examiner states at page 11 of the present Office Action, "The Examiner notes numerous of Applicant's arguments are based on arguments against individual references; for example, page 12 arguments regarding the elements not contained in the housing of Naslund (when Naslund was not cited for this feature)…." The referenced paragraph regarding Naslund at page 12 of Applicants' Amendment of April 13, 2010, is reproduced below.

> Naslund discloses an apparatus for taking samples of cells. The apparatus includes a hand-grip 1 (asserted by the Examiner to be the housing) and a container 4 having a suction plunger 5. A cannula 2 is connected by a hose 3 to the container 4. (Naslund column 2, lines 55-61). The Examiner recognizes that Naslund does not disclose that both the pressure source and the biopsy needle carrier are contained in the housing. More particularly, the pressure source is not contained within the hand-grip 1, but rather extends external to the housing 1 as shown in Fig. 1, and the cannula 2 and the cannula connection 6 (cannula carrier) are external to the hand-grip, and thus also are not contained within the hand-grip 1. (Emphasis added).

While the Examiner stated at page 6 of the Office Action of April 13, 2010, and as repeated in the present Office Action at page 5, that "Naslund does not expressly disclose that both the pressure source and the biopsy needle carrier are contained within the housing", the Examiner also stated at page 5 of the Office Action of April 13, 2010, and as repeated in the

present Office Action at page 4, "Nuslund discloses a biopsy device for tissue collection (Figure 1), comprising: a housing (1) …, and with the pressure source (4 and 5) and the biopsy needle module (2 and 6) being spaced apart in the housing (Figure 1)." (Emphasis added). Here, that which is not conceded by the Examiner is being contested.

Turning to the specific claim language, claim 57 recites, "A biopsy device for tissue collection, comprising: a housing containing a power source; and a removable element, comprising a biopsy needle module and a pressure source, the biopsy needle module having a biopsy needle carrier, wherein the removable element is configured for integration into the housing with both the pressure source and the biopsy needle carrier being contained within the housing and with the pressure source and the biopsy needle module being **spaced apart in** the housing, and a hollow connecting element communicatively coupled between the biopsy needle module and the pressure source." (Emphasis added).

The Examiner states at page 12 of the present Office Action, "The Examiner notes that 'in' in 'the pressure source and the biopsy needle module being spaced apart in the housing' does not require the pressure source and the biopsy needle module are within the housing; as the word 'in' is defined by the dictionary to include 'to or at an appropriate place' and 'near'. Applicants' acknowledge that the dictionary provides alternative definitions for most words, but that does not mean that all alternative meanings are appropriate. Notwithstanding any disagreement of the meaning of the word "in", it should be agreed that "in" would require some portion to be within. Moreover, however, in the phrase "the pressure source and the biopsy needle module being spaced apart in the housing", the word "in" has to do with a location, i.e., in the housing, where pressure source and the biopsy needle module are spaced

apart, and thus necessarily requires that at least a portion of the pressure source and the biopsy needle module that are spaced apart be located in the housing in order to be spaced apart in the housing, notwithstanding what occurs outside the housing.

With the context of claim 57 in mind, Naslund discloses an apparatus for taking samples of cells that includes a hand-grip 1 (asserted by the Examiner to be the housing) and a container 4 having a suction plunger 5. A cannula 2 is connected by a hose 3 to the container 4. (Naslund column 2, lines 55-61). The Naslund pressure source is not contained within the hand-grip 1, but rather extends external to the housing 1 as shown in Fig. 1, and the cannula 2 and the cannula connection 6 (cannula carrier) are external to the hand-grip, and thus also are not contained within the hand-grip 1. Also, the entire spacing of the needle 2/connector 6 and the container 4/plunger 5 is outside housing 1. Further, the Examiner concedes that Naslund does not expressly disclose that both the pressure source and the biopsy needle carrier are contained within the housing.

Gregoire, et al. discloses with respect to Fig. 1 a biopsy instrument 30 that is not operationally self-contained and has cables or lines extending from the housing to external units. More particularly, Gregoire, et al. discloses with respect to Fig. 1 the biopsy instrument 30 having an external vacuum source 86 (not contained within the housing) and an external control unit 87 that are tethered to the probe assembly 45 and the probe driver 31, respectively. (Column 5, lines 21-30). Thus, the entire spacing of the needle module and the pressure source is outside the housing. As shown in Fig. 1, probe driver 31 is configured to receive probe assembly 45 in two opposing slots formed in opposite end walls of the housing of probe driver 31. While two additional opposing slots are shown, neither of the additional

slots receives a portion of the probe assembly 45. Also, probe driver 31 is not a handheld device, as probe driver 31 is mounted to a movable table 20. (Column 5, lines 15-21).

Dejter, Jr. et al. discloses with respect to Figs. 1a-1f schematic illustrations of the positions of a needle 2, a stylet 3, a syringe 4 and a plunger 5, relative to a fixed casing 1 and a needle sheath 6 during a fine needle aspiration procedure. (Column 6, lines 22-26). As illustrated in Fig. 13, the needle 2 is directly connected to syringe 4, and thus needle connector is not spaced apart from syringe 4. As illustrated in Figs. 2, 5 and 7, a finger guide 13 is provided at or near the end of the needle sheath 6 to assist the operator in manipulating the tip of the sheath. Additionally, to facilitate manipulation of the needle assembly, a sheath positioning handle 14 is provided. Handle 14 is attachable (e.g., by snap fit) to the sheath 6 at any desired location along a handle attachment area 12 so as to be positionable for either right or left hand usage and longitudinally adjustable. (Column 8, lines 56-66).

The Examiner cites the three references, Naslund, Gregoire, and Dejter, which taken alone or in combination do not disclose a structure wherein "both the pressure source and the biopsy needle carrier being contained within the housing **and** with the pressure source and the biopsy needle module being spaced apart in the housing". "To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). As the Board of Patent Appeals and Interferences has held:

> "When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). *Ex parte*

> *Wada, et al.*, Appeal 2007-3733 (SN 10/613,220, p. 7 (BPAI 2008) (emphasis in original).

Further, the necessary presence of all claim limitations is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including … ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added).

Further, based on at least the deficiencies of Naslund, Gregoire, and Dejter set forth above as to lack of all limitations, to achieve the invention as recited in claim 57 by the combination of Naslund, Gregoire, and Dejter, significant change in the structure and function of the combined elements of Naslund, Gregoire, and Dejter would have been required because structure would have to be added that is not disclosed, taught or suggested by the references, taken alone or in combination. Thus, the improved structure provided by the present invention over that of Naslund, Gregoire, and Dejter is more than the predictable use of the elements of Naslund, Gregoire, and Dejter according to their established functions. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Accordingly, it is respectfully submitted that claim 57 is patentable in its present form.

Claims 66-68 depend, directly or indirectly, from claim 57 and thus are patentable for reasons set forth above with respect to claim 57.

In addition, each of claims 66-68 is patentable in its own right.

Claim 66 recites, "The biopsy device according to claim 57, wherein the housing comprises a lower housing segment with lateral walls of different heights, a housing lid matched to the lower housing segment and having a longitudinally displaceable locking

mechanism, and a first end lid and a second end lid, each connected to the lower housing segment, wherein the **second end lid** comprises a first U-shape opening and a second U-shape opening, wherein the first U-shape opening is configured to receive a first portion of the removable element and the second U-shape opening is configured to receive a second portion of the removable element." (Emphasis added).

In claim 66 it is recited that the second end lid has the first U-shape opening and the second U-shape opening. Thus, in the structure recited in claim 66, a first portion of the removable element and a second portion of the removable element are received, respectively, in the first U-shaped opening and second U-shaped opening of the same (second) end lid. In contrast, Naslund discloses an arrangement wherein the removable element (needle 2/ pressure source 5) do not intersect any wall more than once, Gregoire discloses a linear arrangement of probe 45 that extends across both end walls of the housing with the pressure source external to the housing and does not intersect any wall more than once, and Dejter discloses a pressure source 4 directly connected in a linear arrangement with the needle 2 that does not intersect any wall more than once.

For at least reasons set forth above, Naslund, Gregoire, et al. and Dejter, taken alone or in combination, do not disclose or suggest all limitations of claim 66, e.g. that "the second end lid comprises a first U-shape opening and a second U-shape opening, wherein the first U-shape opening is configured to receive a first portion of the removable element and the second U-shape opening is configured to receive a second portion of the removable element." Applicants respectfully submit that since all limitations of claim 66 are not disclosed or

suggested by the cited references, taken alone or in combination, a prima facie case of obviousness has not been established. (See case law above with respect to claim 57).

Further, based on at least the deficiencies of Naslund, Gregoire, and Dejter set forth above as to lack of all limitations, to achieve the invention as recited in claim 66 by the combination of Naslund, Gregoire, and Dejter, significant change in the structure and function of the combined elements of Naslund, Gregoire, and Dejter would have been required. Thus, the improved structure provided by the present invention over that of Naslund, Gregoire, and Dejter is more than the predictable use of the elements of Naslund, Gregoire, and Dejter according to their established functions. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Thus, it is respectfully submitted that claim 66 is patentable in its own right.

Claim 67 recites, "The biopsy device according to claim 66, further including a guide disposed on the removable element, wherein the first end lid comprises a third U-shaped opening at the top thereof, the third U-shaped opening being sized to receive the guide of the removable element." The Examiner concedes that the cited references in combination do not disclose the structure of claim 67.

Naslund, Gregoire and Dejter, taken alone or in combination, do not disclose or suggest all limitations of claim 67, namely "a guide disposed on the removable element, wherein the first end lid comprises a third U-shaped opening at the top thereof, the third U-shaped opening being sized to receive the guide of the removable element." Applicants respectfully submit that since all limitations of claim 67 are not disclosed or suggested by the

cited references, taken alone or in combination, a prima facie case of obviousness has not been established. (See case law above with respect to claim 57).

However, in the Office Action of April 13, 2010, the Examiner asserted that it is "well known in the art …to position the guide of the removable element in the front opening of the biopsy device". In the response of July 6, 2010, Applicants requested clarification as to whether Official Notice was being taken. In response, at page 9 of thereof the present Office Action, the Examiner states, "However, the Examiner notes that this limitation is rejected by admitted prior art as Applicant's 6 July 2010 traversal was inadequate (see the Response to Arguments below). In the Response to Arguments of the present Office Action, the Examiner provides at pages 13-16 a discussion of Office Notice which concludes, as follows, "While the Examiner acknowledges Applicant's statements that the noticed fact are not admitted prior art, as the traversal is not adequate for the reasons provided above, the noticed facts are considered admitted prior art because Applicant's traversal was inadequate." While it is now clear that the Examiner was taking Office Notice, such was suspected but was not clear to Applicants until the present action, and thus it is premature to conclude the inadequacy of Applicants' position.

Notwithstanding, MPEP 2144.03A provides that, "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and **unquestionable** demonstration as being well-known." (Emphasis added). At page 15 of the present Office Action, the Examiner states, "The Examiner notes that Figures 2 and 12 (see also Figures 1, 11a-11e and 12f-12h) of Applicant's specification show 'instant and unquestionable

demonstration' of these features; as such, unlike esoteric technologies and theories, these elements and features are capable of 'instant and unquestionable demonstration'."

Clarification is respectfully requested, as it appears the Examiner is taking a position that if an applicant shows an arrangement of components in a drawing in support of the invention, then by default the disclosed structure is subject to Official Notice. Such logic, however, runs counter to the requirements placed on an applicant in satisfying 35 U.S.C. 112, first and second paragraphs, and in providing drawings in support thereof. Thus, it is respectfully submitted that it is improper to use an applicant's own application Figures illustrating the invention to support a position that the Official Notice is proper.

Further, it is not enough that something is "capable of instant and **unquestionable** demonstration", which is taken out of context, but rather, "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are *capable of instant and* ***unquestionable*** *demonstration* **as being well-known**." (MPEP 2144.03A; emphasis added).

As stated in the Amendment of July 6, 2010, and reiterated herein, it is respectfully submitted that the level of structural detail provided by a recitation of "a guide disposed on the removable element, wherein the first end lid comprises a third U-shaped opening at the top thereof, the third U-shaped opening being sized to receive the guide of the removable element", as recited in claim 67 is such that it does not lend itself to "Official Notice" under MPEP 2144.03, as it cannot be instantly and unquestionably demonstrated as being well-known. The fact that the Examiner can find the elements of the claim in the Figures of

Applicants own patent application only demonstrates compliance with provisions of 35 U.S.C., and not support for an inappropriate application of Official Notice.

For the record, the Examiner acknowledges that Applicants expressly do not admit as prior art the structure as recited in claim 67.

Thus, for at least the reasons set forth above, it is respectfully submitted that claim 67 is patentable in its own right.

Claim 68, as amended, recites, "The biopsy device according to claim 57, wherein housing includes a lower housing segment, a housing lid matched to the lower housing segment, a first end lid and a second end lid, each of the first end lid and the second end lid being connected to the lower housing segment, wherein the second end lid comprises a first U-shape opening and a second U-shape opening, wherein the first U-shape opening is configured to receive a first portion of the removable element and the second U-shape opening is configured to receive a second portion of the removable element, and wherein a third portion of the removable element is located between the first U-shape opening and the second U-shape opening external to the housing."

With regard to the subject matter of claim 68, as a first point it is noted that, as set forth in claim 57 from which claim 68 now depends, Naslund, Gregoire, et al. and Dejter, taken alone or in combination, do not disclose a structure wherein the removable element has "both the pressure source and the biopsy needle carrier being contained within the housing **and** with the pressure source and the biopsy needle module being spaced apart in the housing". With the additional limitation of claim 68, "the first U-shape opening is configured to receive a first portion of the removable element and the second U-shape opening is

configured to receive a second portion of the removable element, and wherein a third portion of the removable element is located between the first U-shape opening and the second U-shape opening external to the housing". Thus, in claim 68 the first portion of the removable element and the second portion of the removable element are in the same (second) end lid, and a third portion of the removable element is located between the first U-shape opening and the second U-shape opening external to the housing.

Thus, Naslund, Gregoire, et al. and Dejter, taken alone or in combination, do not disclose or suggest all limitations of claim 68, namely that "the first U-shape opening is configured to receive a first portion of the removable element and the second U-shape opening is configured to receive a second portion of the removable element, and wherein a third portion of the removable element is located between the first U-shape opening and the second U-shape opening external to the housing". Applicants respectfully submit that since all limitations of claim 68 are not disclosed or suggested by the cited references, taken alone or in combination, a prima facie case of obviousness has not been established. (See case law above with respect to claim 57).

Further, based on at least the deficiencies of Naslund, Gregoire, and Dejter set forth above as to lack of all limitations, to achieve the invention as recited in claim 68 by the combination of Naslund, Gregoire, and Dejter, significant change in the structure and function of the combined elements of Naslund, Gregoire, and Dejter would have been required. Thus, the improved structure provided by the present invention over that of Naslund, Gregoire, and Dejter is more than the predictable use of the elements of Naslund, Gregoire, and Dejter

according to their established functions. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Further, only by using impermissible hindsight, and the benefit of Applicants' claim, would one skilled in the art be motivated to use the first U-shaped opening and the second U-shaped opening (of Gregoire) to receive respective portions of the removable element, and with the connecting element being external to the housing, e.g., to complete the fluid path that extends between the two openings, since Naslund, Gregoire, et al. and Dejter, taken alone or in combination, do not disclose a structure wherein the removable element has both the pressure source and the biopsy needle carrier being contained within the housing.

Thus, it is respectfully submitted that claim 68 is patentable in its own right.

Claim 98 recites in part:

> a removable element, comprising a biopsy needle module and a pressure source, the biopsy needle module having a biopsy needle carrier, wherein the removable element is configured for integration into the housing with both the pressure source and the biopsy needle carrier being contained within the housing and with the pressure source and the biopsy needle module being spaced apart in the housing, and a hollow connecting element communicatively coupled between the biopsy needle module and the pressure source;
>
> wherein the biopsy device is configured for single-handed operation by a physician, the biopsy device being configured to be operationally self-contained such that an entirety of the biopsy device can be held by a single hand during a medical procedure, the biopsy device having no cables or lines extending from the housing to external units, and the biopsy device being both held and operated by the same single hand during the medical procedure. (Emphasis added)

It is respectfully submitted that claim 98 is patentable for at least the reasons set forth above with respect to claim 57.

Each of claims 99 and 100 depend, directly or indirectly, from claim 98, and thus is patentable for at least the reasons set forth above with respect to claim 98. In addition, at least claim 100 is patentable in its own right.

Claim 100 recites, "The biopsy device according to claim 98, wherein the second end lid comprises a first U-shape opening and second U-shape opening, wherein each of the first U-shape opening and the second U-shape opening is configured to receive a respective portion of the removable element, with at least a portion of the hollow connecting element being located between the first U-shape opening and the second U-shape opening external to the housing."

As set forth in claim 98 from which claim 100 depends, Naslund, Gregoire, et al. and Dejter, taken alone or in combination, do not disclose a structure wherein the removable element has "both the pressure source and the biopsy needle carrier being contained within the housing and with the pressure source and the biopsy needle module being spaced apart in the housing". With the additional limitation of claim 100, "the second end lid comprises a first U-shape opening and second U-shape opening, wherein each of the first U-shape opening and the second U-shape opening is configured to receive a respective portion of the removable element, with at least a portion of the hollow connecting element being located between the first U-shape opening and the second U-shape opening external to the housing".

Thus, Naslund, Gregoire, and Dejter, taken alone or in combination, do not disclose or suggest all limitations of claim 100, namely that "the second end lid comprises a first U-shape opening and second U-shape opening, wherein each of the first U-shape opening and the second U-shape opening is configured to receive a respective portion of the removable

element, with at least a portion of the hollow connecting element being located between the first U-shape opening and the second U-shape opening external to the housing". Applicants respectfully submit that since all limitations of claim 100 are not disclosed or suggested by the cited references, taken alone or in combination, a prima facie case of obviousness has not been established. (See case law above with respect to claim 57).

Further, based on at least the deficiencies of Naslund, Gregoire, and Dejter set forth above as to lack of all limitations, to achieve the invention as recited in claim 100 by the combination of Naslund, Gregoire, and Dejter, significant change in the structure and function of the combined elements of Naslund, Gregoire, and Dejter would have been required. Thus, the improved structure provided by the present invention over that of Naslund, Gregoire, and Dejter is more than the predictable use of the elements of Naslund, Gregoire, and Dejter according to their established functions. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Only by using impermissible hindsight, and the benefit of Applicants' claim, would one skilled in the art be motivated to use asserted first U-shaped opening and the second U-shaped opening of Gregoire to receive respective portions of the removable element, and with at least a portion of the hollow connecting element located between the first U-shape opening and the second U-shape opening external to the housing, e.g., to complete the fluid path that extends between the two openings, since Naslund, Gregoire, et al. and Dejter, taken alone or in combination, do not disclose a structure wherein the removable element has both the pressure source and the biopsy needle carrier being contained within the housing.

Thus, it is respectfully submitted that claim 100 is patentable in its own right.

Claim 101 recites, in part, "the unitary removable element being configured to be mounted to the housing and received at each of the first U-shape opening, the second U-shape opening and the third U-shape opening, with the pressure source being contained in the housing, and with at least a portion of the hollow connecting element being external to said housing in a region between the first U-shape opening and the second U-shape opening to complete a fluid path that extends between the first U-shape opening and the second U-shape opening external to the housing.

With respect to claim 101, the cited references, taken alone or in combination, do not disclose or suggest a biopsy device wherein the unitary removable element is configured to be mounted to the housing and received at each of the first U-shape opening, the second U-shape opening and the third U-shape opening. Also, the cited references, taken alone or in combination, do not disclose or suggest a biopsy device wherein at least a portion of the hollow connecting element (communicatively coupled between the biopsy needle module and the pressure source contained in the housing) is external to said housing in a region between the first U-shape opening and the second U-shape opening to complete a fluid path that extends between the first U-shape opening and the second U-shape opening external to the housing.

As such, Applicants respectfully submit that since all limitations of claim 101 are not disclosed or suggested by the cited references, taken alone or in combination, a prima facie case of obviousness has not been established. (See case law above with respect to claim 57).

Further, based on at least the deficiencies of Naslund, Gregoire, and Dejter set forth above as to lack of all limitations, to achieve the invention as recited in claim 101 by the

combination of Naslund, Gregoire, and Dejter, significant change in the structure and function of the combined elements of Naslund, Gregoire, and Dejter would have been required. Thus, the improved structure provided by the present invention over that of Naslund, Gregoire, and Dejter is more than the predictable use of the elements of Naslund, Gregoire, and Dejter according to their established functions. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Only by using impermissible hindsight, and the benefit of Applicants' claim, would one skilled in the art be motivated to use openings (of Gregoire) to receive the respective portions of a unitary removable element, and with at least a portion of the hollow connecting element being external to said housing in a region between the first U-shape opening and the second U-shape opening to complete a fluid path that extends between the first U-shape opening and the second U-shape opening external to the housing.

Therefore, for at least the reasons set forth above, it is respectfully submitted that claims 57, 66-68, and 98-101 are patentable under 35 U.S.C. 103(a) over Naslund as modified by Gregoire and Dejter.

Claims 102-104 were rejected under 35 U.S.C. 103(a) as being unpatentable over Naslund as modified by Gregoire and Dejter, and further in view of Jewett (US 3,561,429).

Jewett discloses an instrument for obtaining a biopsy specimen including a syringe-type pressure generator that extends through an opening in the housing, and having a tubing 74 extending from the pressure generator to a tube 75, which cooperate to supply vacuum to tip 81. (Column 4, lines 1-6; Fig. 7).

Claims 102-104 depend, directly or indirectly, from claim 101. Accordingly, it is respectfully submitted that claims 102-104 are patentable over Naslund as modified by Gregoire and Dejter, and further in view of Jewett, since Jewett does not overcome the deficiencies of Naslund as modified by Gregoire and Dejter with respect to claim 101.

In addition, it is respectfully submitted that at least claims 102 and 104 are patentable in their own right.

Claim 102 recites, "The biopsy device of claim 101, wherein the biopsy needle module includes a first component configured to be received by the first U-shape opening and the pressure source includes a second component configured to be received by the second U-shape opening." From claim 101, it is recited that the second end lid has the first U-shape opening and the second U-shape opening, and the first end lid has the third U-shape opening. Thus, in the structure recited in claim 102, the first component of the needle module and the second component of the pressure source are received, respectively, in the first U-shaped opening and second U-shaped opening of the same (second) end lid.

Accordingly, to achieve the invention as recited in claim 102 by the combination of Naslund, Gregoire, Dejter and Jewett, significant change in the structure and function of the combined elements of Naslund, Gregoire, Dejter and Jewett would have been required. Thus, the improved structure provided by the present invention over that of Naslund, Gregoire, Dejter and Jewett is more than the predictable use of the elements of Naslund, Gregoire, Dejter and Jewett according to their established functions. See *KSR International Co. v. Teleflex Inc. (KSR)*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007).

Claim 104 recites, "The biopsy device of claim 103, wherein the biopsy needle module includes a biopsy needle and a cutting sleeve coaxially positioned with respect to the biopsy needle, the biopsy needle module further including a guide roller slidably disposed on said cutting sleeve, the guide roller being received by the first U-shape opening."

The Examiner concedes that the cited references in combination do not expressly disclose the structure of claim 104. However, as stated at page 10 of the present Office Action, the Examiner states, "However, the Examiner notes that this limitation is rejected by admitted prior art as Applicant's 6 July 2010 traversal was inadequate (see the Response to Arguments below), and that a biopsy embodiment in which the cutting sheath is outside the biopsy needle is also admitted prior art for the same reason." While it is now clear that the Examiner was taking Office Notice, such was suspected but was not clear to Applicants until the present action, and thus it is premature to conclude the inadequacy of Applicants' position.

Applicants position with respect to the Examiner's taking of Official Notice is more fully set forth above in the discussion of claim 67, and for brevity will not be repeated here. As stated in the Amendment of July 6, 2010, and being repeated now, it is respectfully submitted that the level of structural detail provided by a recitation of "a guide roller slidably disposed on said cutting sleeve, the guide roller being received by the first U-shape opening" of the housing, is such that it does not lend itself to "Official Notice" under MPEP 2144.03, as it cannot be instantly and unquestionably demonstrated as being well-known.

Accordingly, for at least the reasons set forth above, it is respectfully submitted that claims 102-104 are patentable under 35 U.S.C. 103(a) over Naslund as modified by Gregoire and Dejter, and further in view of Jewett.

In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See*, for example, MPEP §2141.02; *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); and *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983).

Applicants respectfully submit that as a whole, the teachings of cited references, whether taken alone or in combination, fail to render the present invention obvious.

For the foregoing reasons, Applicants submit that the pending claims are patentable over the cited references and are in condition for allowance. Applicants respectfully request withdrawal of all rejections and allowance of the pending claims.

In the event Applicants have overlooked the need for an extension of time, an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No. 50-5242, RONALD K. AUST, P.C.

Should any question concerning any of the foregoing arise, the Examiner is invited to telephone the undersigned at (317) 894-0801.

Respectfully submitted,

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